



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

February 27, 2020

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Casey M. Pehrson
Regulatory Specialist
Decon Labs, INC.
460 Glennie Circle
King of Prussia, PA 19406

Subject: Notification per PRN 98-10 – Update Storage and Disposal Language
Product Name: Cidehol ST
EPA Registration Number: 56753-1
Application Date: 12/13/2019
Decision Number: 558562

Dear Ms. Pehrson:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Perri Moeller at 703-347-8618 or via email at Moeller.Perri@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Kathryn V. Montague".

Kathryn Montague, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

CiDehol® ST

(Gamma Irradiated)

For Use in Clean Rooms and Controlled Areas

Hard Surface Disinfectant

Active Ingredients:

Isopropyl Alcohol CAS# 67-63-070.0%

Other Ingredients:

*Water30.0%

Total:..... 100.0%

*USP Water for Injection

NOTIFICATION

56753-1

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

02/27/2020

KEEP OUT OF REACH OF CHILDREN

DANGER – FLAMMABLE

Keep away from heat or open flame.

Store at room temperature below 48.8°C (120°F)

See other panel for first aid and additional precautions

US EPA Reg. No.: 56753-1

US EPA Est. No.:

Manufactured by:

Decon Labs, Inc.

460 Glennie Circle

King of Prussia, PA 19406

Net Contents: In US XXX oz or gallons

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or Doctor. • Do not give anything to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
<p>Have product container or label with you when calling poison control or doctor, or going for treatment.</p> <p>For emergency information on CiDehol® ST, call the National Pesticides Information Center at 1-800-858-7378, 6:30-4:30 pm Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid breathing vapor or spray mist. Avoid contact with skin or clothing. Wear protective eyewear such as goggles or face shield, protective clothing and chemically resistant gloves. Wash thoroughly with soap and water after handling, before eating, drinking, chewing gum or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS: Flammable liquid and vapor. Keep away from heat or open flame. Exposure to temperatures above 48.8°C (120° F) may cause bursting. Do not mix this product with other chemicals including: acids, oxidizing materials, combustible materials, halogens, peroxides, bases and metal salts.

DIRECTIONS FOR USE

Read the label before using

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

*This product is **NOT** to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.*

USE: Disinfects and sanitizes clean rooms and controlled areas such as those used in healthcare institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on hard non-porous inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tables, counters, laminar flow benches, floors, walls, carts, shelves made of hard non-porous materials, such as, glass, plastic, vinyl, chrome, and stainless steel. It is compatible with most hard surface materials.

DISINFECTION: Use this product while wearing personal protection. Wear protective eyewear such as goggles or face shield, protective clothing and chemically resistant gloves. Use with adequate ventilation and spray away from eyes and face. *CiDehol® ST* is ready to use. Do not dilute. Pre-clean surface or item of heavy soil or gross filth before application. Hold container upright 6-8 inches from surface. Spray product on surface and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth, wiper, if needed.

CiDehol® ST is bactericidal. The results of AOAC Efficacy Tests show that *CiDehol® ST* is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC#6538), and *Salmonella enterica* (ATCC#10708) in the presence of 5% fetal bovine serum organic load in 10 minutes.

SANITIZATION: Use 5 minute contact time on hard, non-porous surfaces (made from: stainless steel, glass, Corian™, laminate flooring, aluminum, pvc, mild steel, polypropylene), in isolators, clean rooms, sterile and controlled areas, gowning rooms and on process lines, gloves, work surfaces, tools and equipment.

CiDehol® ST is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATCC#6538) and *Enterobacter aerogenes* (ATCC#13048) in the presence of 5% fetal bovine serum organic load in 5 minutes.

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Storage: Store in the original container in a dry cool place below 48.8°C (120° F).

Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticides (rinsate). ~~Triple rinse (or equivalent).~~ After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. ~~If not triple-rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations.~~

Lot number/ Batch Code: XXXXX

EXPIRY: MONTH/YEAR.